

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

AMERICAN ACADEMY OF PEDIATRICS, et al.,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

Civil Action No.
8:18-cv-883-PWG

BRIEF OF AMERICAN THORACIC SOCIETY, AMERICAN MEDICAL ASSOCIATION, AMERICAN ACADEMY OF ALLERGY, ASTHMA AND IMMUNOLOGY, AMERICAN ASSOCIATION FOR RESPIRATORY CARE, AMERICAN COLLEGE OF CHEST PHYSICIANS, AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE, AMERICAN COLLEGE OF PREVENTIVE MEDICINE, AMERICAN PUBLIC HEALTH ASSOCIATION, NATIONAL ASSOCIATION FOR THE MEDICAL DIRECTION OF RESPIRATORY CARE, NATIONAL CENTER FOR HEALTH RESEARCH, AND NATIONAL MEDICAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS

KATHLEEN HOKE (BAR No. 11220)
PROFESSOR, UNIVERSITY OF MARYLAND
FRANCIS KING CAREY SCHOOL OF LAW
500 West Baltimore Street,
Baltimore, MD 21201
(410) 706-1294
khoke@law.umaryland.edu

RACHEL BLOOMEKATZ
DEEPAK GUPTA
GUPTA WESSLER PLLC
1900 L Street, NW, Suite 312
Washington, DC 20036
(202) 888-1741
rachel@guptawessler.com

July 17, 2018

Counsel for Amici Curiae

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INTRODUCTION AND STATEMENT OF INTEREST¹

Have you ever heard of a Unicorn Milk e-cigarette or a Da Bomb Blueberry cigarillo? These products—and the many like them—represent an entirely new generation of tobacco products. They are often made with sweet flavors, are designed to look like juice boxes or candy, and many are small enough to be hidden in a teenager’s palm or back pocket. And they are getting a new generation addicted to nicotine. Parents today might not find a pack of Camels in their kids’ backpacks, but instead JUUL—an e-cigarette that looks just like a USB flash drive. JUUL is a tiny device that heats up a cartridge containing nicotine liquid—often in a flavor with a catchy name—that creates a vapor inhaled by the user.² (See image p. 17 *infra*.) It is a “sensation” among teens and a “nightmare” for teachers, parents, and school administrators.³ The 2016 Surgeon General’s Report declares that “e-cigarette use among U.S. youth and young adults is now a major public health concern.”⁴ And the proliferation of flavored and mini cigars (known as cigarillos) means that high school boys are now as likely to smoke cigars as cigarettes, with more than 2,500 young people smoking their first cigar each day.⁵

¹ All parties have consented to the filing of this amicus brief. No counsel of any party to this proceeding authored any part of this brief. No party or party’s counsel, or person other than *amici* and their members, contributed money to the preparation or submission of this brief. Descriptions of each individual *amicus* are included in the Addendum.

² Truth Initiative, *What is JUUL?* (Feb. 5, 2018), available at <https://perma.cc/AU3M-KH58>.

³ Kaiser Health News, *Why Juuling Has Become A Nightmare for School Administrators*, NBC (Mar. 18, 2018), available at <https://perma.cc/BL8G-AHLE>.

⁴ Office on Smoking & Health, Dep’t of Health & Human Servs., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, vii (2016), available at <https://perma.cc/SS67-G7LD> (hereinafter “SGR”).

⁵ The 2014 National Survey on Drug Use and Health found that more than 2,500 youth under the age of 18 smoke their first cigar each day, nearly as many as those who smoke their first cigarette each day (more than 2,600). Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and

As medical practitioners and public health experts, the *amici* here see the devastating public health impact of these new tobacco products every day. The *amici* are eleven nonprofit groups of medical professionals and researchers that, based on their scientific expertise and professional experience, are particularly well-suited to explain to the Court the dangers of these yet-unregulated products—particularly the health effects of cigars and e-cigarettes—and their increasing prevalence among youth. The scientific evidence of their dangers, especially to youth, is overwhelming.⁶

In enacting the Tobacco Control Act, Congress sought to stem the tide of tobacco-related illness and death. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1777 (2009) (recognizing that “[t]obacco use is the foremost preventable cause of premature death in America” and that reducing youth tobacco use could save millions of lives). It prohibited tobacco companies from selling new tobacco products (*i.e.*, those introduced after February 15, 2007) unless the manufacturer could prove to the Food and Drug Administration (FDA) that the products were either “substantially equivalent” to those that were commercially available in 2007 or that allowing their sale would be “appropriate for the protection of the public health” under standards set forth in the statute. 21 U.S.C. § 387j (2018). And the FDA, with its 2016 Deeming Rule, deemed e-cigarettes, cigars, and other tobacco products within the scope of the Act’s mandates, including these “premarket” review requirements. DR at 28,977. So, do these new tobacco products pass Congress’s test? Is the Unicorn Milk e-cigarette or the Da

Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973, 28,985 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143) (hereinafter “DR”).

⁶ Many of the sources for this brief come from the Deeming Rule and its administrative record. Other sources are the type that many *amici* would have included in comments had the agency properly promulgated this policy through notice and comment. As to the most recent sources, “a court need blind itself to such events.” *See Amoco Oil Co. v. EPA*, 501 F.2d 722, 729 n.10 (D.C. Cir. 1974).

Bomb Blueberry cigarillo “substantially equivalent” to a product on the market in 2007? Is permitting their sale “appropriate for the protection of public health”?

The FDA has no answer. And it cannot say until it begins collecting and reviewing the industry’s “premarket” applications for these “new” tobacco products, some of which have been on the marketplace already for over a decade. Receipt of premarket-review applications for cigars and e-cigarettes—detailing what the tobacco product contains, how it is designed, and information about its health effects—has been delayed again and again by the agency. The FDA’s Guidance at issue in this case delays premarket application deadlines set by the Deeming Rule for combustibles like cigars to 2021 and non-combustibles like e-cigarettes to 2022. Guidance at 3, 8.⁷ By that point, some of these addictive nicotine products will have enjoyed unfettered access to the market for at least *fourteen years*. And that’s just the delay until the manufacturer has to submit the application; once it’s submitted, the product stays on the market until the FDA makes a decision that it does not meet the Tobacco Control Act’s requirements. Guidance at 3. The result: the Guidance allows these dangerous products to thrive on the market without review for an indefinite period of time.

It is neither lawful nor reasonable for the FDA to abdicate its statutory obligations for so many years. The public health consequences alone explain why. As the FDA has itself recognized, there is an “alarming rise” in the popularity of unregulated tobacco products among “middle school and high school students.” DR at 29,028. If this agency delay continues, a full generation of adolescents will be at risk of a lifetime of addiction. That’s the opposite of what Congress

⁷ Food & Drug Admin., *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Guidance for Industry (Revised)* (4th Ed., Nov. 2017), available at <https://perma.cc/DT2Z-X4FK> (hereinafter “Guidance”).

legislated with the Tobacco Control Act, and it is arbitrary and capricious. Accordingly, *amici* respectfully request that the Court grant the plaintiffs' motion for summary judgment.

ARGUMENT

I. The proliferation of flavored and mini cigars threatens public health, particularly for youth.

Because of the FDA's Guidance, cigars—one of the most dangerous tobacco products—will evade premarket review for years, if not decades. The cigars that *amici* witness flooding the market are not your grandfather's stogies. They are new, flavored, and often mini cigars (or cigarillos) that appeal to youth and new tobacco users because they make the harsh taste of tobacco more palatable. And, unlike cigarettes, they can be purchased one or two at a time for under a dollar.⁸ Consequently, consumption of cigars exceeds cigarettes for many key youth demographics. Overall, while cigarette use has fallen, cigar use is on the rise.⁹ Most critically, much like cigarettes, smoking these new cigars and cigarillos leads to nicotine addiction, cancer, heart disease, lung disease, stroke, and death.

A. Cigar smoking increases the risk of devastating health conditions and death, and it has particularly troubling medical consequences for youth.

Just like smoking cigarettes, the devastating health consequences of cigar smoking are well-established. “All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users.” DR at 29,020. Users also experience an “increased risk of heart and pulmonary disease,” particularly chronic obstructive pulmonary disease. *Id.*

⁸ Patti Neighmond, *Sweet Cigarillos and Cigars Lure Youth to Tobacco, Critics Say*, NPR (Aug. 26, 2013), *available at* <https://n.pr/2zHowRA>.

⁹ Campaign for Tobacco Free Kids, Fact Sheet, “The Rise of Cigars and Cigar-Smoking Harms,” *available at* <https://perma.cc/FW4L-487M> (citing Economic Research Service, U.S. Department of Agriculture, U.S. Alcohol and Tobacco Tax and Trade Bureau, Tobacco Statistics).

Compared to nonsmokers, the risk of both fatal and nonfatal strokes also increases with cigar smoking. *Id.* All told, cigar smoking is “responsible for approximately 9,000 premature deaths”—or the loss of “almost 140,000 years of potential life”—every year. *Id.*

Given all that is known about the health effects of smoking cigarettes, the devastating health effects of smoking cigars is no surprise. Just like cigarettes, cigars contain tobacco and nicotine—and burning them creates an array of dangerous chemicals. *Id.* In fact, the FDA reported that a single “cigar can contain as much tobacco as a whole pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette.” *Id.* at 29,022. Exposure to secondhand cigar smoke “can cause the same or similarly dangerous effects as exposure to secondhand cigarette smoke.” *Id.* at 29,071. And, in comparison to cigarette smoke, cigar smoke often contains more tar, carbon monoxide, ammonia, lead, cadmium, and nitrosamines. *Id.* at 29,070. There are good reasons behind why the FDA has ordered that cigars carry bold government warnings: they are addictive, they cause cancer and other diseases, and they lead to death.¹⁰

The health effects on youth are particularly grave because nicotine exposure at a young age “may have lasting adverse consequences for brain development.” DR at 29,033; *see also* SGR at vii (reporting that adolescents—whose brains are not yet fully developed—are particularly “vulnerable to the negative consequences of nicotine exposure.”). Neuroscience research over the past few decades has shown that, contrary to earlier assumptions, brain development continues

¹⁰ Most cigar labels and advertisements carry warnings pursuant to a 2000 settlement agreement between the Federal Trade Commission and the seven largest U.S. cigar manufacturers. The Deeming Rule mandates larger warnings, which are scheduled to take effect in August, but have been delayed by a legal challenge. DR at 29,015; Nate Raymond, *Federal Judge Delays FDA Cigar Warning Label Requirement*, Reuters (July 6, 2018) *available at* <https://perma.cc/Q7K8-2H8R>.

into one's twenties (when it is legal to purchase cigars).¹¹ Because nicotine exposure at this younger age induces structural changes in the brain, those who begin to use tobacco as adolescents are more likely to smoke into adulthood, have more difficulty quitting, and experience deeper levels of addiction. SGR at 105. Beyond addiction and “priming for use of other addictive substances,” the effects include “reduced impulse control, deficits in attention and cognition, and mood disorders.” *Id.* at vii; *see also* DR at 29,023, 29,033.

B. The tobacco industry's new strategy pushes flavored and mini cigars, increasing addiction by youth.

The health effects of cigars were concerning even when use was thought to be largely confined to older men smoking an occasional cigar in lounges. But that is not what cigar use is like now. The new cigars that have entered the market—those over which the FDA is bound by statute to conduct “premarket” review—come in all sorts of candy and fruit flavors and more closely resemble cigarettes than ever before. No wonder that among youth they are catching up in popularity to cigarettes. DR at 29,023.

Tobacco manufacturers have long understood that flavors are a critical means of initiating users—and adolescents in particular—to tobacco products. *See* SGR at 11 (“Flavors have been used for decades to attract youth to tobacco products and to mask the flavor and harshness of tobacco.”). Because of the Tobacco Control Act, the tobacco industry can no longer sell flavored cigarettes in the U.S. (except menthol). 21 U.S.C. § 387g (2018). But there is no prohibition on flavored cigars.¹² Accordingly, since the Tobacco Control Act, tobacco

¹¹ *See* Elizabeth S. Scott & Laurence Steinberg, *Rethinking Juvenile Justice* 44 (2010) (“Scientists have found clear evidence that the brain continues to mature through adolescence and into the early twenties, with large-scale structural change taking place during this period.”).

¹² In the Deeming Rule, the FDA stated that it “intends in the future to issue a proposed product standard that, if finalized, would eliminate characterizing flavors in all cigars including cigarillos and little cigars.” DR at 29,024. However, the FDA has since indicated that it may be

manufacturers have been quick to modify cigars to imitate cigarettes in size and appearances—and then they add the flavorings. These PrimeTime “wild berry” little cigars are one example:



The industry is not even discrete about using such flavored cigars as a gateway product to get people hooked. The vice president of marketing for the international division of Swedish Match, which sells White Owl Cigars and Game Cigars, stated: “It is mainly new recruits to cigar smoking who take to the new flavors, while long-time consumers still prefer the more traditional cigars.”¹³ The luxury lifestyle magazine, *Cigar Aficionado*, reported: “flavored cigars serve as a bridge to premium cigars for the uninitiated, something to be smoked as an entryway into the world of cigar smoking. For the novice, a simple, sweet and easily identifiable flavor (honey or cherry, for example) is an easier step than moving into a box marked Cuban-seed Corojo.”¹⁴ And tobacco industry documents show “that tobacco companies marketed flavored little cigars and cigarillos to youth and to African Americans to facilitate their uptake of cigarettes.” SGR at 11.

reconsidering the issue, as it issued a new advanced notice of proposed rulemaking on the subject. *See* 83 Fed. Reg. 12,294 (Mar. 21, 2018).

¹³ Swedish Match, “No. 2 worldwide in cigars,” (March 7, 2007), *available at* <https://perma.cc/C4RW-8VC4>.

¹⁴ Savona, D, “Cigars of a Different Flavor,” *Cigar Aficionado* (July/August 2005); *see* “Campaign for Tobacco Free Youth, In their own words: What cigar companies, retailers, and analysts say about cheap and kid-friendly products,” *available at* <https://perma.cc/XC5E-7T4D>.

The hope, then, for the tobacco industry is for smaller and cheaper flavored cigarillos to lead to greater tobacco use over time.

The result: a proliferation of flavored cigars and cigarillos. Flavored cigar sales have skyrocketed by 50 percent since 2008 and now make up half of the entire cigar market.¹⁵ Since 2008, the number of unique cigar flavors on the market has more than doubled from 108 to 250.¹⁶ And if ‘fun’ flavor names like Maui Pineapple and Cherry Dynamite are not enough to attract customers, shiny reflective packaging resembling a candy wrapper only magnifies their appeal:



The modern cigar industry’s focus on youth was well summed up by one study cited by the FDA: according to a focus group of 14- to 18-year-olds, “cigars were easy to obtain,” “new brands were

¹⁵ Cristine D. Delnevo, et al., *Changes in the Mass-merchandise Cigar Market since the Tobacco Control Act*, Tob. Regul. Sci. (April 2017), available at <https://perma.cc/KDR8-CREE>. See also Campaign for Tobacco Free Kids, “Flavor Trap: How tobacco companies are luring kids with candy-flavored e-cigarettes and cigars” (March 15, 2017), available at <https://perma.cc/5844-XQ67>.

¹⁶ Delnevo, *supra*, at 4.

targeting youth,” and “the products were prominent in rap videos.” 79 Fed. Reg. 23,141, 23,158 (Apr. 25, 2014).

The strategy has paid off for the industry—all to the detriment of public health. More and more young people are smoking cigars each day that the FDA does not act. High school boys are now as likely to smoke cigars as cigarettes. DR at 29,023. The FDA itself reported that more than 2,500 young people under the age of 18 smoke their first cigar each day. DR at 28,985. That means that each year that the Guidance delays premarket review, almost one million youth try this deadly product, potentially starting on the path to a deadly addiction. *See also* 79 Fed. Reg. at 23,156 (reporting that more than one million people between the age of 12 and 18 initiated cigar use in 2010, and that number increased in 2011). Moreover, the FDA recognized that “[m]easures of youth use of cigars may underestimate prevalence due to incorrect self-identification as a non-cigar smoker and confusion between the various cigar products.” DR at 29,023.

Cigarillo popularity has also exploded in many urban communities.¹⁷ Philadelphia, for example, has seen teen cigar and “cigarillo” usage rise by more than 75 percent between 2011 and 2015.¹⁸ According to the 2014 National Youth Tobacco Survey (“NYTS”), the number of African American high school students that reported smoking cigars in the past thirty days was nearly double the number of students that reported smoking cigarettes in that period (8.8% to 4.5%). DR at 29,023. In these communities, cigars are no longer an “alternative” to cigarettes, but a primary tobacco product of preference.

¹⁷ Amy L. Nyman, et al., *Little Cigars and Cigarillos: Users, Perceptions, and Reasons for Use*, 2 Tobacco Regul. Sci. 239 (2016).

¹⁸ Josephine Hwang & Brian Jenssen, *The Problem with Kids and Flavored Tobacco*, Philadelphia Enquirer (June 21, 2018), *available at* <https://perma.cc/85MH-RTQC>.

II. The increasing prevalence of e-cigarettes and other electronic nicotine delivery systems threaten public health.¹⁹

The Surgeon General, opening his 2016 report, declared that “[e]-cigarette use among U.S. youth and young adults is now a major public health concern.” SGR at vii. And even the Department of Justice, representing the FDA before the D.C. Circuit this spring, admitted that the widespread use and potential harm of e-cigarettes necessitated government regulation. *See* Brief of FDA, *Nicopure Labs v. FDA*, No. 17-5196 (D.C. Cir., filed May 2, 2018). It warned: “The available data suggest that many of these products present substantial risks, and *regulation is necessary* both to address those harms and to resolve uncertainty about the products’ effects.” *Id.* at 13 (emphasis added). *Amici* agree with the DOJ/FDA there. But in its Guidance at issue in this case, the FDA delays this “necessary” regulation for, in some circumstances, fourteen years or more. This delay of premarket review is incompatible with its necessity. And, as with cigars, the public health effects of e-cigarettes are particularly striking among youth.

Importantly, while in this section *amici* focus on the proliferation of youth e-cigarette use and problematic marketing of e-cigarettes by some manufacturers and distributors, they also recognize the numerous other potential public health concerns associated with e-cigarettes that the FDA must consider in the premarket review process. These include dangerously poor product quality (that can lead to fires and explosions),²⁰ child poisonings from nicotine

¹⁹ In this brief, *amici*’s reference to e-cigarettes includes all electronic nicotine delivery systems that are not approved by the FDA as smoking cessation devices.

²⁰ The batteries and other components used in e-cigarettes pose health and safety risks. Media reports have chronicled serious injuries—including facial burns and lost teeth—attributed to exploding batteries. *See* DR at 29,035. The U.S. Fire Administration found 25 media reports of e-cigarette explosions or fires between 2009 and 2014, and it concluded that the shape of e-cigarettes makes them more likely to shoot off like “flaming rockets” when a battery fails. FEMA, *Electronic Cigarette Fires and Explosions in the United States 2009-2016* (July 2017), available at <https://perma.cc/Z9R5-V3VG>. The U.S. Department of Transportation recently banned e-cigarettes from checked luggage, after fires at Boston Logan and LAX showed that the devices

exposure,²¹ the use of ingredients (particularly flavorants) that are particularly dangerous to inhale,²² the ability of users to modify the product in hazardous ways,²³ and more. Without premarket review, the FDA does not have the information needed to assess—much less address—these public health issues.

A. The rise of e-cigarette use among youth is a major public health concern.

Although e-cigarettes were not a focus of the 2009 Tobacco Control Act, the FDA realized soon thereafter that they raised potential public health concerns. When the D.C. Circuit ruled in 2010 that the FDA could not regulate e-cigarettes as drugs, *Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010), the FDA quickly announced its intent to regulate them through the

“can overheat and cause fires when the heating element is accidentally activated or turned on.” 80 Fed. Reg. 66,817, 66,817–18 (Oct. 30, 2015). *See also* Susan F. Rudy & Elizabeth L. Durmowicz, *Electronic nicotine delivery systems: overheating, fires and explosions*, 26 Tobacco Control 10 (2016), available at <https://perma.cc/5ZCX-NZH3> (catalogue of e-cigarette explosion incidents since 2009).

²¹ Alisha Kamboj, et al., *Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States*, Pediatrics (May 2016), available at <https://perma.cc/CL8C-39C5> (the monthly number of calls to the National Poison Data System relating to e-cigarette exposures increased by nearly 1500% between 2012 and 2015).

²² What information is available about ingredients used in e-liquids also shows that many present health concerns. Many e-liquids contain chemicals that pose known risks, including formaldehyde, diacetyl and acetyl propionyl, and various aldehydes. DR at 29,029–31. *See also* Jessica L. Barrington-Trimis, et al., *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?*, JAMA (Dec. 2014), available at <https://bit.ly/2LpNaYv>. And the ingredients change based on the type of e-liquid. For example, a study of 159 e-liquids with sweet flavors (such as “toffee, chocolate, and caramel”) found that “almost three quarters of the samples (74 percent) contained diacetyl or acetyl propionyl, both of which pose known inhalation risks.” DR at 29,029. A second study, of 30 e-liquids, “found that many flavors, including cotton candy and bubble gum, contain aldehydes, a class of chemicals that can cause respiratory irritation [and] airway constriction,” and noted that “two flavors, a dark chocolate and a wild cherry, would expose e-cigarette users to more than twice the recommended workplace safety limit for the aldehydes vanillin and benzaldehyde.” *Id.* A third study found that several cinnamon-flavored e-liquids contained yet another aldehyde, “cinnamaldehyde, which [is] highly toxic to human cells in laboratory tests.” *Id.*

²³ Suchitra Krishnan-Sarin, et al., *E-cigarettes and ‘Dripping’ Among High-School Youth*, Pediatrics (Feb. 2017), available at <https://perma.cc/KAT7-E4SN>.

deeming process, specifically noting the need for premarket review.²⁴ That was already more than seven years ago.

Since then, the need for regulation has not dissipated. To the contrary, youth use of e-cigarettes has exploded. The use of these products has surged among middle and high school students in particular, including those with no history of smoking, DR at 28,984–85, 29,028–29, and e-cigarettes are now the tobacco product most commonly used by young people. 83 Fed. Reg. at 12,296. “Overall, according to the NYTS, ever use of e-cigarettes among students in grades 6–12 increased from 3.3% in 2011, to 6.8% in 2012, to 8.1% in 2013, to 19.8% in 2014, and then to 27% in 2015”—a more than 700% *increase* in only four years. SGR at 28. Other surveys found even higher levels of youth use. *Id.* “According to data from the 2015 Youth Risk Behavior Survey (YRBS), a larger percentage of high school students (44.9%) had ever [tried] e-cigarettes.” *Id.* Past 30-day use among 6th–12th graders followed a similarly trajectory, increasing from 1.1% in 2011 to 11.3% in 2015. *Id.* at 36. And, according to the Surgeon General, this equated to past-month e-cigarette use by an estimated 620,000 middle school students and 2,390,000 high school students. *Id.* at 28. Though youth e-cigarette use appears to have decreased somewhat in the past two years,²⁵ these products are still “the most commonly used form of tobacco among youth in the United States, surpassing conventional tobacco products, including cigarettes, cigars, chewing tobacco, and hookahs.” *Id.* at vii.

This explosion of e-cigarette use is introducing a whole new generation to nicotine and nicotine addiction. As noted above with respect to cigars, adolescents—whose brains are not yet

²⁴ See Letter to Stakeholders: Regulation of E-cigarettes and Other Tobacco Products, April 26, 2011, from Lawrence R. Deyton, Director of FDA’s Center for Tobacco Products, and Janet Woodcock, Director of the FDA’s Center for Drug Evaluation and Research.

²⁵ See Teresa W. Wang, et al., *Tobacco Product Use Among Middle and High School Students—United States, 2011–2017*, Centers for Disease Control & Prevention, 67 Morbidity & Mortality Weekly Report 629 (June 8, 2018), *available at* <https://perma.cc/7PQE-HQPF>.

fully developed—are particularly vulnerable to nicotine exposure, and there is emerging evidence (discussed further below) that e-cigarette use is a gateway to smoking. The current FDA Commissioner, Scott Gottlieb, just months ago announced that “nicotine in these [e-cigarette] products can rewire an adolescent’s brain, leading to years of addiction.”²⁶ The result is an “epidemic” in schools across the nation, where school administrators must struggle with their students’ addiction to nicotine from e-cigarettes.²⁷ One school counselor summed it up: “I think this is going to be the health problem of the decade.”²⁸

Without premarket review, the e-cigarette market continues to evolve in ways that are problematic for youth. Take, for example, the “JUUL” e-cigarette brand. The manufacturer, Juul Labs, Inc., was founded in 2015 and is already worth more than \$16 billion.²⁹ JUULs have “gone viral” on high school campuses because the product “looks like a USB flash drive [and] even charges when plugged into a laptop” and is “small enough to fit inside an enclosed hand, and comes with flavors like creme brulee, mango and fruit medley.”³⁰ By using patented nicotine salts, they also “appear[] to deliver nicotine more quickly, more effectively and at higher doses

²⁶ Statement from FDA Comm’ner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes (Apr. 24, 2018), *available at* <https://perma.cc/LU8P-ESE8>.

²⁷ See Anne Marie Chaker, *Schools and Parents Fight a Juul E-Cigarette Epidemic*, Wall Street Journal (Apr. 4, 2018), *available at* <https://on.wsj.com/2IoTE81>; Kate Zernike, *‘I Can’t Stop’: Schools Struggle With Vaping Explosion*, NY Times (Apr. 2, 2018), *available at* <https://nyti.ms/2Ed693Y>.

²⁸ Kaiser Health News (Mar. 18, 2018), *supra*.

²⁹ Olivia Zaleski, *E-Cigarette Maker Juul Labs Is Raising \$1.2 Billion*, Bloomberg (June 29, 2018), *available at* <https://perma.cc/84FL-FJEZ>.

³⁰ Josh Hafner, *Juuling is popular with teens, but doctor sees a ‘good chance’ that it leads to smoking*, USA Today (Oct. 31, 2017), *available at* <https://perma.cc/VZ4L-M4WX>; Angus Chen, *Teenagers Embrace JUUL, Saying It’s Discreet Enough To Vape In Class*, NPR (Dec. 4, 2017), *available at* <https://n.pr/2nAqHQQ>.

than other e-cigarettes, increasing users' risk of addiction.”³¹ Commissioner Gottlieb recently noted the “surging youth uptake of JUUL and other products,” and stated that the “FDA must—and will—move quickly to reverse these disturbing trends.”³² Despite this commitment, and Congress's clear directive, because of the Guidance these products will not be subject to premarket review until at least 2022.

B. The e-cigarette industry uses flavors and marketing techniques to attract youth.

The proliferation of e-cigarette use among youth is not surprising, considering the types of flavors and marketing techniques that e-cigarette manufacturers employ to sell their product. Although sales to minors are illegal, companies nonetheless have strong economic incentives to maximize their products' attractiveness to youth, just as cigarette companies (many of which are now also selling e-cigarettes) did in the past.³³ And just like cigarette companies used flavors and marketing techniques to target kids, e-cigarette companies are doing the same. Congress, through the Tobacco Control Act, sought to stem the public health crisis caused by “Big Tobacco.” But the e-cigarette companies' techniques closely mirror the tobacco industry's shameful history of targeting youth.

1. E-cigarette flavors appeal to youth. As the Surgeon General has stated, “[t]he widespread availability and popularity of flavored e-cigarettes is a key concern regarding the potential public health implications of the products.” SGR at 11. That's particularly true because

³¹ Campaign for Tobacco Free Kids, “Industry Watch: JUUL E-Cigarettes: A New Threat To Kids”, *available at* <https://perma.cc/79CN-CPCX>.

³² Statement from FDA Comm’ner Scott Gottlieb (Apr. 24, 2018), *supra*.

³³ Campaign for Tobacco Free Kids, “Tobacco Company Marketing to Kids”, *available at* <https://perma.cc/3KW5-756Q> (compilation of tobacco industry actions and quotations regarding marketing to children, including Philip Morris statement that “[t]oday’s teenager is tomorrow’s potential regular customer,” and Lorillard Tobacco statement that “the base of our business is the high school student.”).

flavors appear to be a major driver of youth use. Sweet-flavored e-cigarettes varieties, in particular, magnify the products' attractiveness to young people. *See* DR at 29,011. In a 2015 study, more than 80% of current youth e-cigarette users said that they used e-cigarettes “because they come in flavors I like.”³⁴ They have plenty to choose from.

Unlike conventional cigarettes, “which are permitted in only two characterizing flavors—tobacco and menthol—a staggering 4,000 to 8,000 different varieties of e-liquid (or 5,000 to 10,000 unique packaging configurations) are now sold in the United States.” D.R. 29,011.³⁵ E-cigarette liquids that are “bound to send your taste buds into overdrive” include fruity and dessert-like best-selling flavors, such as:³⁶

- Unicorn Milk (strawberries and cream)
- TNT (strawberry, apple, and peach)
- I Love Donuts (blueberries and pastry)
- Wild Watermelon
- Summer Peach
- FruitApalooza

The images below provide some additional examples of flavored products that some experts are concerned may appeal to youth:



³⁴ Bridget K. Ambrose, et al., *Flavored tobacco product use among U.S. youth aged 12–17 years, 2013–2014*, 314 JAMA 1871 (Nov. 3, 2015), available at <https://bit.ly/2HXLDKJ>.

³⁵ As of 2017, researchers had identified more than 15,500 unique e-cigarette flavors available for sale online. Greta Hsu, et al., *Evolution of Electronic Cigarette Brands from 2013–2014 to 2016–2017: Analysis of Brand Websites*, 20 J. Med. Internet Res. e80 (Mar. 12, 2018), available at <https://bit.ly/2LhbOO0>.

³⁶ *See* list of Nicopure's offerings at <https://www.halocigs.com/e-liquid/fruit-flavors> and the top three selling flavors from E-Liquids.com, a large online retailer, at <http://eliquid.com/collections/best-sellers>.

Should the FDA allow these products? The Guidance means that we don't know—at least for years upon years. Meanwhile, thousands of products with thousands of flavors (including flavors that may appeal to youth) remain on the market indefinitely. The Guidance thwarts the entire prereview process, which is essential for “the protection of the public health.” 21 U.S.C. § 387j.

2. E-cigarette marketing mimics “Big Tobacco” marketing techniques.

Beyond flavors, the marketing practices of some e-cigarette companies are deeply concerning. Like the use of flavors, e-cigarette advertising appears to target youth, “mimicking,” in the DOJ's words, “the strategies previously used by ‘Big Tobacco’—to devastating effect—and thus banned for conventional cigarettes.”³⁷ For instance, although cigarette companies have long been prohibited from advertising their products on television, e-cigarette ads have been “strategically targeted to reach youth through network placement on television stations with clear youth appeal such as Comedy Central, ABC Family, and MTV.”³⁸ E-cigarette companies “air advertisements during events and programming with high levels of youth viewership,” like the Super Bowl and the Academy Awards.³⁹ As the Surgeon General noted, e-cigarette manufacturers are using many of the promotional techniques that the 1998 Master Settlement Agreement prohibited for conventional cigarettes because of their tendency to induce youth tobacco use. These include advertising in magazines with high levels of youth readership, sponsoring sporting events and concerts, placing ads at the eye level of children in retail locations, and paying for product

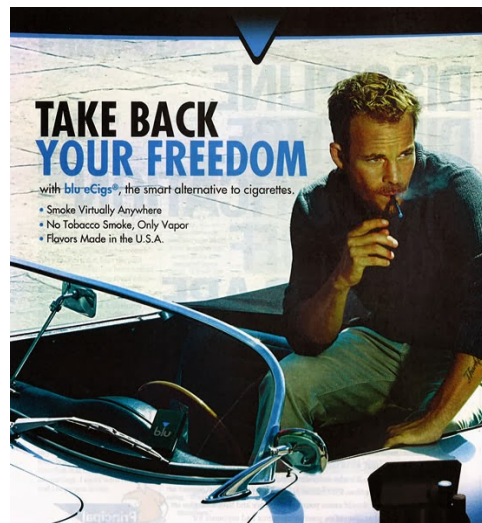
³⁷ Memorandum in Opposition to Plaintiffs' Motions for Summary Judgement and in Support of Defendants' Cross-Motion for Summary Judgment, *Nicopure Labs, LLC v. FDA and Right to be Smoke-Free Coalition v. FDA (consolidated)*, CA Nos. 16-878, 16-1210, 15, (D.D.C. filed August 16, 2016).

³⁸ Campaign for Tobacco Free Kids, “Electronic Cigarettes and Youth,” *available at* <https://perma.cc/LTA4-ZKCC>.

³⁹ Staff of Senator Richard J. Durbin, et al., *Gateway to Addiction: A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*, 16 (Apr. 24, 2014).

placement in TV shows and movies. SGR at 15, 159, 168. The new flood of online e-cigarette advertising—through online “banner” advertising and social media such as YouTube, Instagram, and Facebook—compounds the impact. *Id.* at 166–67.

The messages these advertisements and promotions carry recycle Big Tobacco’s old playbook. They often use celebrity endorsements “to depict e-cigarette smoking as glamorous, rebellious, sexy, and masculine.”⁴⁰ Claims of lifestyle benefit—a hallmark of traditional tobacco advertising—are also common. A study of 59 e-cigarette websites showed that 73 percent made claims that e-cigarettes are modern or glamorous, 44 percent pointed to increased social status, 32 percent suggested enhanced social activity, 31 percent alluded to romantic advantages, and 22 percent used celebrities.⁴¹ As the Surgeon General summarized, “[t]hemes in e-cigarette marketing, including sexual content and customer satisfaction, are parallel to themes and techniques that have been found to be appealing to youth and young adults in conventional cigarette advertising and promotion.” SGR at 172. No wonder they seem familiar:



⁴⁰ *Id.* at 17.

⁴¹ R.A. Grana & P.M. Ling, ‘Smoking Revolution’: a content analysis of electronic cigarette retail websites, 46 Am. J. Pre. Med. 395, 399 (Apr. 2014), available at <https://bit.ly/2Llsm4h>.

Do people—including youth—just ignore these ads? The answer appears to be no. The evidence demonstrates that the more one sees these ads, the more one is likely to use e-cigarettes. As the Surgeon General explained: “The plethora of unregulated advertising is of particular concern, as exposure to advertising for tobacco products among youth is associated with cigarette smoking in a dose-response fashion.” SGR at 15. And without premarket review, youth are seeing a lot of these advertisements.

C. Studies demonstrate that e-cigarettes lead to cigarette use, not that they support smoking cessation.

E-cigarette advocates suggest that any youth use of e-cigarettes is unfortunate, but its overwhelmed by the public health benefits of having smokers move to a less-harmful product. The evidence for this proposition, however, simply is not there. The National Academy of Sciences (“NAS”) review found that “[o]verall, there is *limited evidence* that e-cigarettes may be effective aids to promote smoking cessation.”⁴² The U.S. Preventive Services Task Force, which sets the standards for which smoking cessation services are covered under the Affordable Care Act, has similarly concluded that there is “insufficient evidence” to recommend e-cigarettes as a cessation tool.⁴³ There is nothing to stop any e-cigarette manufacturer from presenting the FDA with evidence that the product is an effective cessation device and seeking authorization to make such claims. To date however, no e-cigarette company has done so. If anything, e-cigarettes may prevent cessation. As the DOJ recently argued: “[S]tudies suggest that cigarette

⁴² National Academies of Sciences, Engineering & Medicine, *Public Health Consequences of E-Cigarettes*, 10 (Jan. 23, 2018), available at <https://perma.cc/M8C7-2HE3> (hereinafter “NAS”) (emphasis in original).

⁴³ U.S. Preventative Task Force, *Final Recommendation Statement: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions* (Sept. 2017), available at <https://perma.cc/9TCL-2DFP>.

smokers who also use e-cigarettes are less likely to quit smoking than cigarette smokers who do not also use e-cigarettes.” Brief of FDA, *supra*, at 16 (citing DR at 28,988).

On the other hand—as the FDA has further conceded—the evidence appears to be clear and growing that youth e-cigarette use is a gateway into the use of other tobacco products. *See id.* at 16–17. The NAS report concluded that there is “**substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco use among youth and young adults.” NAS at 10 (emphasis in original). Similarly, the Surgeon General noted that “[f]ive longitudinal studies to date suggest that e-cigarette use among youth and young adults might lead to initiation of the use of combustible tobacco products in the future.” SGR at 56. That body of evidence has only continued to grow since the Surgeon General’s Report was completed,⁴⁴ and it raises the specter that the proliferation of youth e-cigarette use could, over time, undermine our nation’s progress in reducing smoking rates.

Such claims, at any rate, only underscore the need for premarket review of these products—a review that is now being further delayed by the Guidance. It is illegal, unreasonable, and devastating for the public health for the FDA to postpone its oversight obligations any further.

CONCLUSION

For these reasons, the Court should grant the plaintiffs’ motion for summary judgment.

⁴⁴ Samir Soneji, et al., *Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Youth Adults: A Systematic Review and Meta-analysis*, 171 JAMA Pediatrics 788 (Aug. 2017), available at <https://bit.ly/2Ldkk0u> (updated meta-analysis concluding that there is “consistent and strong evidence that e-cigarette use is associated with increased odds of subsequent cigarette smoking initiation and current cigarette smoking among adolescents and young adults after adjusting for known demographic, psychosocial, and behavioral risk factors.”).

Respectfully submitted,

/s/ Kathleen Hoke

RACHEL BLOOMEKATZ
DEEPAK GUPTA
GUPTA WESSLER PLLC
1900 L Street, NW, Suite 312
Washington, DC 20036
(202) 888-1741
rachel@guptawessler.com

KATHLEEN HOKE (BAR NO. 11220)
PROFESSOR, UNIVERSITY OF MARYLAND
FRANCIS KING CAREY SCHOOL OF LAW
500 West Baltimore Street,
Baltimore, MD 21201
(410) 706-1294
khoke@law.umaryland.edu

July 17, 2018

Counsel for Amici Curiae

ADDENDUM: IDENTITY OF *AMICI CURIAE*

American Thoracic Society

Founded in the 1905, the American Thoracic Society is a medical professional society comprised of over 16,000 physicians, scientists, nurses, respiratory therapists and allied health professionals dedicated to the prevention, detection, treatment, cure and research of pulmonary disease, critical care illness and sleep disordered breathing. Our members seek to improve health through research, education, clinical care and advocacy. As respiratory experts, our members are all too familiar with disease, death, and emotional destruction caused by tobacco products.

American Medical Association

The American Medical Association (AMA) is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all US physicians, residents and medical students are represented in the AMA's policy making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every state and in every medical specialty.

American Academy of Allergy, Asthma and Immunology

The American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with nearly 7,000 members in the United States, Canada, and 72 other countries dedicated to the advancement of the knowledge and practice of allergy, asthma, and immunology for optimal patient care. As such, AAAAI is dedicated to reducing and/or preventing the effects of tobacco on allergy, asthma, and immunology patients.

American Association for Respiratory Care

The American Association for Respiratory Care encourages and promotes professional excellence, advances the science and practice of respiratory care, and serves as an advocate for patients, their families, the public, the profession, and the respiratory therapist. It is the leading national and international professional association for respiratory care with a membership of over 47,000 respiratory therapists who treat patients with chronic respiratory disease. Respiratory therapists specialize in the promotion of optimum cardiopulmonary function, health, and wellness, practicing under medical direction across the health care continuum.

American College of Chest Physicians

The American College of Chest Physicians is the global leader in advancing best patient outcomes through innovative chest medicine education, clinical research, and team-based care. With more than 19,000 members representing 100+ countries around the world, our mission is to champion the prevention, diagnosis, and treatment of chest diseases through education, communication and research. As such CHEST is dedicated to the prevention of tobacco-related diseases.

American College of Occupational and Environmental Medicine

Established in 1916, the American College of Occupational and Environmental Medicine (ACOEM) is an international society of 4,500 occupational and environmental medicine (OEM) physicians. The OEM physician has the knowledge and skills to provide evidence-based clinical

evaluation and treatment of injuries and illnesses that are occupationally and/or environmentally related. In addition, the OEM physician's skill and expertise includes understanding health risks, clinical practice guidelines for chronic disease management, and current practices in disease detection, prevention, and treatment. Members of ACOEM have the ability to assess the causes and occupational impact of respiratory disorders and pulmonary impairment.

American College of Preventive Medicine

The American College of Preventive Medicine (ACPM) is the medical society for physician specialists with expertise in both clinical care and population health. The College advances the practice of preventive medicine in public health and health systems, and advocates for health policies that work to prevent disease, promote health, and avert health crises in individuals, communities, and defined populations. ACPM is a leader in disease prevention, including preventing diseases related to tobacco use.

American Public Health Association

The American Public Health Association (APHA) champions the health of all people and all communities, strengthens the profession of public health, shares the latest research and information, promotes best practices, and advocates for public health policies grounded in research. APHA represents over 20,000 individual members and is the only organization that combines a nearly 150-year perspective and a broad-based member community with an interest in improving the public's health. APHA advocates for tobacco control measures to protect the public's health from the adverse effects of tobacco products.

National Association for the Medical Direction of Respiratory Care

The primary mission of the National Association for the Medical Direction of Respiratory Care (NAMDRC) is to improve access to quality care for patients with respiratory disease by removing regulatory and legislative barriers to appropriate treatment. NAMDRC supports efforts to reduce tobacco-related disease and addiction through effective regulation of all tobacco products.

National Center for Health Research

The National Center for Health Research (NCHR) performs original health research and reviews scientific and medical studies to better inform public policy decision makers. NCHR investigates drug and medical device safety issues, participates on FDA advisory committee public sessions, and advocates for patients and consumers, while accepting no industry funds.

National Medical Association

As the nation's oldest and largest organization representing African American physicians and health professionals in the United States, the National Medical Association (NMA) has led the fight for better medical care and opportunities for all Americans, with a strong focus on health issues related to communities of color and the medically underserved, including the targeting of young people of color with tobacco advertising and increased availability of flavored tobacco products. The NMA is dedicated to reducing and eliminating disparities in health and improving the lives of our patients, their families, and their communities.

CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2018, I electronically filed the foregoing brief with the Clerk of the Court of the District Court of Maryland by using the CM/ECF system. All participants are registered CM/ECF users, and will be served by the Appellate CM/ECF system.

/s/ Kathleen Hoke
Kathleen Hoke